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HEADLINE: House Panel Chief Seeks Data From Makers of Stents and Drugs

BYLINE: By Reuters

BODY:

The chairman of a House committee has asked two medical device companies and three drug makers for documents as part of an investigation into product safety and marketing practices.

Representative Henry A. Waxman, Democrat of California and chairman of the House Oversight and Government Reform Committee, asked Boston Scientific and Johnson & Johnson for information on their drug-coated stents to treat clogged heart arteries, citing concerns about the safety and off-label use of the devices.

Off-label use of medical devices and drugs occurs when doctors use the products to treat ailments other than those for which they are approved by regulators.

Mr. Waxman also sought information about allegations of inappropriate marketing by the drug makers Eli Lilly & Company, AstraZeneca and Cephalon.

The letter to Eli Lilly requested information about a schizophrenia drug, Zyprexa, citing allegations that the company "misled physicians and inappropriately promoted off-label uses" of the drug. The company's efforts to encourage Zyprexa for off-label uses like treating dementia was the subject of an article last year in The New York Times.

The AstraZeneca letter sought details about its schizophrenia drug, Seroquel. Mr. Waxman's letter to Cephalon asked for information about the narcotic painkillers Actiq and Fentora.

He asked all three drug makers and the two stent makers for lists of studies conducted on each product as well as documents related to marketing plans, among other information.

Press officers for the drug makers could not immediately be reached for comment.

In separate brief statements, Boston Scientific and J.& J. said they would provide the information requested. Spokesmen for both companies declined to comment further on the letters.

Drug-coated stents are small, medicated wire-mesh tubes inserted into diseased arteries after they have been unclogged. They have come under increased scrutiny after research showed the devices can cause blood clots months after implantation.

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Sales of the devices have softened recently doctors and patients have reassessed the risks.

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